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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,610	01/27/2004	Gregory J. LaRosa	1855.1052-029	3808

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,610	LAROSA ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/27/2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 9, 10, 13-15, and 22 (in part), drawn to an isolated nucleic acid, expression vector, and a fused gene encoding a humanized immunoglobulin light chain, classified in class 536, subclass 23.53.

II. Claims 5-8, 11, 12, 16-18, 22 (in part), drawn to an isolated nucleic acid, expression vector, and a fused gene encoding a humanized immunoglobulin heavy chain, classified in class 536, subclass 23.53.

III. Claim 19, drawn to a host cell, an isolated nucleic acid, expression vector, and a fused gene encoding a humanized immunoglobulin heavy and light chain, classified in class 536, subclass 23.53.

IV. Claims 20 and 21, drawn to a method of preparing a humanized immunoglobulin, whereby human immunoglobulin chains are expressed and a humanized immunoglobulin is produced, classified in class 435, subclass 69.6.

V. Claims 23-26 and 60, drawn to a method of inhibiting the interaction of a first cell expressing CCR2 and a second cell expressing a ligand of CCR2, classified in class 435, subclass 334.

VI. Claims 27-30 and 61, drawn to a method of treating HIV in a patient, and inhibiting HIV infection in a patient, classified in class 435, subclass 334.

VII. Claims 31-32, 62, drawn to a method of inhibiting a function associated with binding of a chemokine to mammalian CCR2 or a functional portion of CCR2, classified in class 435, subclass 334.

VIII. Claims 33-35, drawn to a method of inhibiting leukocyte trafficking in a patient, classified in class 435, subclass 334.

IX. Claims 36-37, 53-56, 63, drawn to a method of treating a CCR2- mediated disorder in a patient, classified in class 435, subclass 334.

If Group IX is elected, the Applicant is further required to elect **one** medical disorder in a patient from the following: multiple sclerosis, rheumatoid arthritis, atherogenesis, and atherosclerosis.

X. Claim 38 and 43, 44-52, 64, drawn to a method of inhibiting restenosis in patient, classified in class 435, subclass 334.

If Group X is elected, the Applicant is further required to elect **one** medical disorder in a patient.

XI. Claims 39, 41, and 65, drawn a humanized immunoglobulin light chain, classified in class 530, subclass 387.1.

If Group XI is elected, the Applicant is further required to elect **one** sequence: SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 98, or SEQ ID NO: 107.

XII. Claims 40, and 42, drawn to a humanized immunoglobulin heavy chain, classified in class 530, subclass 387.1.

If Group XII is elected, the Applicant is further required to elect **one** sequence: SEQ ID NO: 17, SEQ ID NO: 18 SEQ ID NO: 19, SEQ ID NO: 20, or SEQ ID NO: 97.

XIII. Claims 57-59, drawn a humanized immunoglobulin or antigen–binding fragment thereof having binding specificity for CCR2 comprising heavy and light chain, classified in class 530, subclass 387.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination specifies the use of SEQ ID NO: 9. The subcombination has separate utility such as in a method to induce an immune response.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP §

806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination specifies the use of SEQ ID NO: 10. The subcombination has separate utility such as in a method to induce an immune response.

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. See MPEP § 806.05(d).

In the instant case, the nucleic acid of Group I and the nucleic acid of Group II encode different products. The nucleic acid of Group I encodes a protein from the light chain of an antibody, while the nucleic acid of Group II encodes a protein from the heavy chain of the same antibody. The encoded proteins are not obvious over each other because their amino acid sequences are different. The subcombinations of Groups I and II have separate utilities. The nucleic acid of Group I can be used in a method of epitope mapping. The nucleic acid of Group II can be used in a method of inducing an immune response.

The nucleotides and the polypeptides of Group (I, II, III and XI, XII, XIII) and the methods of Groups (IV, V, VI, VII, VIII, IX, and X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. The nucleotides and the polypeptides of Group (I, II, III and XI, XII, XIII) can be used for other purposes than to build a construct, which will serve as building blocks in a method of preparing a humanized immunoglobulin of Group IV. For example the nucleotides can be used as a probe for detection of nucleic acids in the sample, and the peptides can be used to generate specific immune responses in a patient. The nucleotides and the polypeptides of Group (I, II, III and XI, XII, XIII) can be used for other purposes than using them in a method of inhibiting the interaction of a first cell expressing CCR2 and a second cell expressing a ligand of CCR2 of Group V, a method of treating HIV in a patient of Group VI, a method of inhibiting a function associated with binding of a chemokine to mammalian CCR2 of Group VII, a method of inhibiting leukocyte trafficking in a patient of Group VIII, a method of treating a CCR2- mediated disorder in a patient of Group IX, a method of inhibiting restenosis in patient of Group X. A search for nucleic acid and peptide sequences and polypeptides of Groups (I, II, III and XI, XII, XIII) is not co-extensive with a search for method of preparing a humanized immunoglobulin of Group IV, or any other methods in Groups V-X. Searching more than one invention and searching all nucleic acid sequences together would present an undue burden for the examiner. Therefore restriction for examination purposes is proper.

The nucleic acids of Groups (I, II, III) and polypeptides comprising immunoglobulin light or heavy chain of Groups (XI, XII, XIII) are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the information provided by the polynucleotide of Groups (I, II, III) could be used to make a materially different peptide than that of Group XI or XII. For example the polynucleotide sequence that hybridizes to SEQ ID NO: 9 will not encode the peptide SEQ ID NO: 12. In addition, while a peptide of Group XI can be made by methods using some, but not all, of the polynucleotides that fall within the scope of Group I, it can also be recovered from a natural source using by biochemical means. For instance, by isolating the immunoglobulins from the blood and digesting the light and heavy chains apart. For these reasons, the inventions of Groups (I, II, III) and (XI, XII, XIII) are patentably distinct.

Furthermore, searching the inventions of Groups (I, II, III) and (XI, XII, XIII) together would impose a serious search burden. In the instant case, the search of the

peptide and the polynucleotides are not coextensive. The inventions of Groups (I, II, III) and (XI, XII, XIII) have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to peptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. The scope of nucleotides as claimed extends beyond the polynucleotide that encodes the claimed peptides as explained above; furthermore, a search of the nucleic acid molecules of SEQ ID NO: 9 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the distinct sequences of Group XI. In addition, searching all nucleotide and peptide sequences would be burdensome and requires using commercial databases. Therefore restriction for examination purposes as indicated is proper.

Inventions IV, V, VI, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).). In the instant case the different inventions are drawn to seven different methods, method of preparing a humanized immunoglobulin of Group IV, a method of inhibiting the interaction of a first cell expressing CCR2 and a second cell expressing a ligand of

CCR2 of Group V, a method of treating HIV in a patient of Group VI, a method of inhibiting a function associated with binding of a chemokine to mammalian CCR2 of Group VII, a method of inhibiting leukocyte trafficking in a patient of Group VIII, a method of treating a CCR2- mediated disorder in a patient of Group IX, and a method of inhibiting restenosis in a patient of Group X. These methods have different method steps and use different reagents. A search for a method one method is not co-extensive with a search for any other method. In addition even though in some cases the classification is shared, the different search would be required based upon the different method steps and different diseases aimed to be treated with different methods. For example, the literature search, required for Group VI, regarding a method of treating HIV in a patient would not necessarily reveal the literature regarding the a method of inhibiting restenosis in a patient of Group X. It is an undue burden for the examiner to search more than one invention. Additionally searching for methods of treatment for different diseases listed in claims 43-56 would be an undue burden for the examiner, therefore restriction for examination purposes is proper.

Because the inventions are distinct for the reasons given above and the literature and sequence search required for one group is not co-extensive with any other group, and therefore presents a serious burden of search, restriction for examination as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on M – F (9:00AM - 6:00PM).
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen
March 6, 2006

Stacy B Chen 3/6/06

Stacy B. Chen
Patent Examiner
Art Unit 1648